

105TH CONGRESS
2D SESSION

S. 2208

To amend title IX of the Public Health Service Act to revise and extend the Agency for Healthcare Policy and Research.

IN THE SENATE OF THE UNITED STATES

JUNE 23, 1998

Mr. FRIST introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To amend title IX of the Public Health Service Act to revise and extend the Agency for Healthcare Policy and Research.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Healthcare Quality
5 Enhancement Act of 1998”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents for this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

Sec. 3. Amendment to the Public Health Service Act.

“TITLE IX—AGENCY FOR HEALTHCARE QUALITY

“PART A—ESTABLISHMENT AND GENERAL DUTIES

“Sec. 901. Mission and duties.

“Sec. 902. General authorities.

“PART B—HEALTHCARE IMPROVEMENT RESEARCH

“Sec. 911. Healthcare outcome improvement research.

“Sec. 912. Private-public partnerships to improve organization and delivery.

“Sec. 913. Information on quality and cost of care.

“Sec. 914. Information systems for healthcare improvement.

“Sec. 915. Research supporting primary care and access in underserved areas.

“Sec. 916. Clinical practice and technology innovation.

“Sec. 917. Coordination of Federal Government quality improvement efforts.

“PART C—GENERAL PROVISIONS

“Sec. 921. Advisory Council for Healthcare Quality.

“Sec. 922. Foundation for Healthcare Research.

“Sec. 923. Peer review with respect to grants and contracts.

“Sec. 924. Certain provisions with respect to development, collection, and dissemination of data.

“Sec. 925. Dissemination of information.

“Sec. 926. Additional provisions with respect to grants and contracts.

“Sec. 927. Certain administrative authorities.

“Sec. 928. Funding.

“Sec. 929. Definitions.

Sec. 4. References.

1 **SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE**

2 **ACT.**

3 Title IX of the Public Health Service Act (42 U.S.C.

4 299 et seq.) is amended to read as follows:

5 **“TITLE IX—AGENCY FOR**
6 **HEALTHCARE QUALITY**

7 **“PART A—ESTABLISHMENT AND GENERAL**
8 **DUTIES**

9 **“SEC. 901. MISSION AND DUTIES.**

10 “(a) IN GENERAL.—There is established within the
11 Public Health Service an agency to be known as the Agen-

1 cy for Healthcare Quality. In carrying out this subsection,
2 the Secretary shall redesignate the Agency for Healthcare
3 Policy and Research as the Agency for Healthcare Quality.

4 “(b) MISSION.—The purpose of the Agency is to en-
5 hance the quality, appropriateness, and effectiveness of
6 healthcare services, and access to such services, through
7 the establishment of a broad base of scientific research
8 and through the promotion of improvements in clinical
9 practice, including the prevention of diseases and other
10 health conditions. The Agency shall promote healthcare
11 quality improvement by—

12 “(1) conducting and supporting research that
13 develops and presents scientific evidence regarding
14 all aspects of healthcare, including—

15 “(A) the development and assessment of
16 methods for the purposes of enhancing patient
17 participation in their own care and for facilitat-
18 ing shared patient-physician decision-making;

19 “(B) the outcomes, effectiveness, and cost-
20 effectiveness of healthcare practices, including
21 preventive measures and primary care;

22 “(C) existing and innovative technologies;

23 “(D) the costs and utilization of, and ac-
24 cess to healthcare;

1 “(E) the ways in which healthcare services
 2 are organized, delivered, and financed and the
 3 interaction and impact of these factors on the
 4 quality of patient care;

5 “(F) methods for measuring quality and
 6 strategies for improving quality; and

7 “(G) ways in which patients, consumers,
 8 and practitioners acquire new information
 9 about best practices and health benefits, and
 10 the determinants of their use of this informa-
 11 tion;

12 “(2) synthesizing and disseminating available
 13 scientific evidence for use by patients, consumers,
 14 practitioners, providers, purchasers, policy makers,
 15 and educators; and

16 “(3) advancing private and public efforts to im-
 17 prove healthcare quality.

18 “(c) REQUIREMENTS WITH RESPECT TO RURAL
 19 AREAS AND PRIORITY POPULATIONS.—In carrying out
 20 subsection (b), the Director shall undertake and support
 21 research, demonstration projects, and evaluations with re-
 22 spect to—

23 “(1) the delivery of health services in rural
 24 areas (including frontier areas);

1 “(2) health services for low-income groups, and
2 minority groups;

3 “(3) the health of children;

4 “(4) the elderly; and

5 “(5) people with special healthcare needs, in-
6 cluding chronic care and end-of-life healthcare.

7 “(d) APPOINTMENT OF DIRECTOR.—There shall be
8 at the head of the Agency an official to be known as the
9 Director for Healthcare Quality. The Director shall be ap-
10 pointed by the Secretary. The Secretary, acting through
11 the Director, shall carry out the authorities and duties es-
12 tablished in this title.

13 **“SEC. 902. GENERAL AUTHORITIES.**

14 “(a) IN GENERAL.—In carrying out section 901(b),
15 the Director shall support demonstration projects, conduct
16 and support research, evaluations, training, research net-
17 works, multi-disciplinary centers, technical assistance, and
18 the dissemination of information, on healthcare, and on
19 systems for the delivery of such care, including activities
20 with respect to—

21 “(1) the quality, effectiveness, efficiency, appro-
22 priateness and value of healthcare services;

23 “(2) quality measurement and improvement;

1 “(3) the outcomes, cost, cost-effectiveness, and
2 use of healthcare services and access to such serv-
3 ices;

4 “(4) clinical practice, including primary care
5 and practice-oriented research;

6 “(5) healthcare technologies, facilities, and
7 equipment;

8 “(6) healthcare costs, productivity, and market
9 forces;

10 “(7) health promotion and disease prevention,
11 including clinical preventive services;

12 “(8) health statistics, surveys, database devel-
13 opment, and epidemiology; and

14 “(9) medical liability.

15 “(b) HEALTH SERVICES TRAINING GRANTS.—The
16 Director may provide training grants in the field of health
17 services research related to activities authorized under
18 subsection (a), to include pre- and post-doctoral fellow-
19 ships and training programs, young investigator awards,
20 and other programs and activities as appropriate. In car-
21 rying out this subsection, the Director shall make use of
22 funds made available under section 478.

23 “(c) MULTIDISCIPLINARY CENTERS.—The Director
24 may provide financial assistance to assist in meeting the
25 costs of planning and establishing new centers, and oper-

1 ating existing and new centers, for multidisciplinary
2 health services research, demonstration projects, evalua-
3 tions, training, and policy analysis with respect to the mat-
4 ters referred to in subsection (a).

5 “(d) RELATION TO CERTAIN AUTHORITIES REGARD-
6 ING SOCIAL SECURITY.—Activities authorized in this sec-
7 tion may include, and shall be appropriately coordinated
8 with experiments, demonstration projects, and other relat-
9 ed activities authorized by the Social Security Act and the
10 Social Security Amendments of 1967. Activities under
11 subsection (a)(2) of this section that affect the programs
12 under titles XVIII and XIX of the Social Security Act
13 shall be carried out consistent with section 1142 of such
14 Act.

15 “(e) DISCLAIMER.—Nothing in this title shall be con-
16 strued to imply that the Agency’s role is to mandate na-
17 tional standards of clinical practice or quality healthcare
18 standards. Recommendations resulting from projects
19 funded and published by the Agency shall include a cor-
20 responding disclaimer.

21 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
22 tion shall be construed to imply that the Agency’s role is
23 to mandate a national standard or specific approach to
24 quality measurement and reporting. In research and qual-
25 ity improvement activities, the Agency shall consider a

1 wide range of choices, providers, healthcare delivery sys-
 2 tems, and individual preferences.

3 **“PART B—HEALTHCARE IMPROVEMENT**

4 **RESEARCH**

5 **“SEC. 911. HEALTHCARE OUTCOME IMPROVEMENT RE-**
 6 **SEARCH.**

7 “(a) EVIDENCE RATING SYSTEMS.—In collaboration
 8 with experts from the public and private sector, the Agen-
 9 cy shall identify and disseminate methods or systems used
 10 to assess healthcare research results, particularly—

11 “(1) to rate the strength of the scientific evi-
 12 dence behind healthcare practice and technology rec-
 13 ommendations in the research literature; and

14 “(2) to assess the quality and currency of
 15 health related information available on the Internet
 16 and other electronic media.

17 The Agency shall make methods or systems for evidence
 18 rating widely available. Agency publications containing
 19 healthcare recommendations shall indicate the level of sub-
 20 stantiating evidence using such methods or systems.

21 “(b) HEALTHCARE IMPROVEMENT RESEARCH CEN-
 22 TERS AND PROVIDER-BASED RESEARCH NETWORKS.—

23 “(1) IN GENERAL.—In order to address the full
 24 continuum of care and outcomes research, to link re-
 25 search to practice improvement, and to speed the

dissemination of research findings to community practice settings, the Agency shall employ research strategies and mechanisms that will link research directly with clinical practice in geographically diverse locations throughout the United States, including—

“(A) Healthcare Improvement Research Centers that combine demonstrated multidisciplinary expertise in outcomes or quality improvement research with linkages to relevant sites of care;

“(B) Practice-based Research Networks, including plan, facility, or delivery system sites of care (especially primary care), that can evaluate and promote quality improvement; and

“(C) other innovative mechanisms or strategies.

“(2) REQUIREMENTS.—The Director is authorized to establish the requirements for entities applying for grants under this subsection.

“(c) EXPANSION OF THE HEALTH SERVICES RESEARCH WORKFORCE.—

“(1) GRANTS.—The Agency shall, through the awarding of grants, support eligible entities at geographically diverse locations throughout the United States to enable such entities to carry out research

1 training programs that are dedicated to health serv-
 2 ices research training at the doctoral, post-doctoral,
 3 and junior faculty levels.

4 “(2) REQUIREMENTS.—In developing priorities
 5 for the allocation of training funds under this sub-
 6 section, the Director shall take into consideration
 7 shortages in the number of trained researchers ad-
 8 dressing the priority populations.

9 **“SEC. 912. PRIVATE-PUBLIC PARTNERSHIPS TO IMPROVE**
 10 **ORGANIZATION AND DELIVERY.**

11 “(a) SUPPORT FOR EFFORTS TO DEVELOP INFOR-
 12 MATION ON QUALITY.—

13 “(1) SCIENTIFIC AND TECHNICAL SUPPORT.—
 14 In its role as the principal agency for healthcare
 15 quality research, the Agency shall provide scientific
 16 and technical support for private and public efforts
 17 to improve healthcare quality, including accrediting
 18 organizations.

19 “(2) ROLE OF THE AGENCY.—With respect to
 20 paragraph (1), the role of the Agency shall include—

21 “(A) the identification and assessment of
 22 methods for the evaluation of the health of en-
 23 rollees in health plans by type of plan, provider,
 24 and provider arrangements;

1 “(B) the ongoing development, testing, and
 2 dissemination of quality measures, including
 3 measures of health and functional outcomes,
 4 that take into account appropriate variations in
 5 individual preferences;

6 “(C) the compilation and dissemination of
 7 healthcare quality measures developed in the
 8 private and public sector;

9 “(D) assistance in the development of im-
 10 proved healthcare information systems;

11 “(E) the development of survey tools for
 12 the purpose of measuring participant and bene-
 13 ficiary assessments of their healthcare; and

14 “(F) the integration of information on
 15 quality into purchaser and consumer decision-
 16 making processes.

17 “(b) DEMONSTRATION PROGRAM REGARDING CEN-
 18 TERS FOR EDUCATION AND RESEARCH ON THERA-
 19 PEUTICS.—

20 “(1) IN GENERAL.—The Secretary, acting
 21 through the Director and in consultation with the
 22 Commissioner of Food and Drugs, shall establish a
 23 demonstration program for the purpose of making
 24 one or more grants for the establishment and oper-

1 ation of one or more centers to carry out the activi-
2 ties specified in paragraph (2).

3 “(2) REQUIRED ACTIVITIES.—The activities re-
4 ferred to in this paragraph are the following:

5 “(A) The conduct of state-of-the-art clini-
6 cal research for the following purposes:

7 “(i) To increase awareness of—

8 “(I) new uses of drugs, biological
9 products, and devices;

10 “(II) ways to improve the effec-
11 tive use of drugs, biological products,
12 and devices; and

13 “(III) risks of new uses and risks
14 of combinations of drugs and biologi-
15 cal products.

16 “(ii) To provide objective clinical in-
17 formation to the following individuals and
18 entities:

19 “(I) Healthcare practitioners and
20 other providers of Healthcare goods or
21 services.

22 “(II) Pharmacy benefit managers
23 and purchasers.

1 “(III) Health maintenance orga-
2 nizations and other managed
3 healthcare organizations.

4 “(IV) Healthcare insurers and
5 governmental agencies.

6 “(V) Patients and consumers.

7 “(iii) To improve the quality of
8 healthcare while reducing the cost of
9 Healthcare through—

10 “(I) the appropriate use of drugs,
11 biological products, or devices; and

12 “(II) the prevention of adverse
13 effects of drugs, biological products,
14 and devices and the consequences of
15 such effects, such as unnecessary hos-
16 pitalizations.

17 “(B) The conduct of research on the com-
18 parative effectiveness, cost-effectiveness, and
19 safety of drugs, biological products, and devices.

20 “(C) Such other activities as the Secretary
21 determines to be appropriate, except that a
22 grant may not be expended to assist the Sec-
23 retary in the review of new drugs.

24 “(3) APPLICATION FOR GRANT.—A grant under
25 paragraph (1) may be made only if an application

1 for the grant is submitted to the Secretary and the
 2 application is in such form, is made in such manner,
 3 and contains such agreements, assurances, and in-
 4 formation as the Secretary determines to be nec-
 5 essary to carry out this section.

6 “(4) PEER REVIEW.—A grant under paragraph
 7 (1) may be made only if the application for the
 8 grant has undergone appropriate technical and sci-
 9 entific peer review.

10 “(c) RESEARCH ON HEALTHCARE BENEFITS.—

11 “(1) PURPOSE.—The Director is authorized to
 12 conduct and support research to evaluate the impact
 13 of changes in healthcare benefits.

14 “(2) CONSIDERATIONS.—In carrying out para-
 15 graph (1), the Director shall build partnerships with
 16 appropriate public and private sector entities to re-
 17 view available scientific evidence and undertake such
 18 evaluations. As appropriate and to the extent that
 19 data are available, the evaluation shall consider—

20 “(A) safety and effectiveness, including
 21 health and functional outcomes of patients;

22 “(B) costs, benefits, and cost-effectiveness;
 23 and

24 “(C) comparisons with alternative clinical
 25 approaches.

1 “(d) REDUCING ERRORS IN MEDICINE.—The Direc-
2 tor shall conduct and support research and build private-
3 public partnerships to—

4 “(1) identify the causes of preventable
5 healthcare errors and patient injury in healthcare
6 delivery systems;

7 “(2) develop, demonstrate, and evaluate strate-
8 gies for reducing errors and improving patient safe-
9 ty; and

10 “(3) promote the implementation of effective
11 strategies throughout the healthcare industry.

12 **“SEC. 913. INFORMATION ON QUALITY AND COST OF CARE.**

13 “(a) IN GENERAL.—In carrying out 902(a), the Di-
14 rector shall—

15 “(1) collect data from a nationally representa-
16 tive sample of the population on the cost and use of
17 healthcare, including the types of healthcare services
18 Americans use, their access to healthcare services,
19 frequency of use, how much is paid for the services
20 used, the source of those payments, the types and
21 costs of private health insurance, access, satisfac-
22 tion, and quality of care for the general population
23 and also for children, uninsured persons, poor and
24 near-poor individuals, and persons with special
25 healthcare needs, including end-of-life healthcare;

1 “(2) develop databases and tools that enable
2 States to track the quality, access, and use of
3 healthcare services provided to their residents; and

4 “(3) enter into agreements with public or pri-
5 vate entities to use, link, or acquire databases for re-
6 search authorized under this title.

7 “(b) QUALITY AND OUTCOMES INFORMATION.—

8 “(1) IN GENERAL.—To enhance the under-
9 standing of the quality of care, the determinants of
10 health outcomes and functional status, the needs of
11 special populations as well as an understanding of
12 these changes over time, their relationship to
13 healthcare access and use, and to monitor the overall
14 national impact of Federal and State policy changes
15 on healthcare, the Director, beginning in fiscal year
16 2000, shall ensure that the survey conducted under
17 subsection (a)(1) will—

18 “(A) provide information on the quality of
19 care and patient outcomes for frequently occur-
20 ring clinical conditions for a nationally rep-
21 resentative sample of the population; and

22 “(B) provide reliable national estimates for
23 children and persons with special healthcare
24 needs through the use of supplements or peri-
25 odic expansions of the survey.

1 “(2) ANNUAL REPORT.—Beginning in fiscal
2 year 2002, the Secretary, acting through the Direc-
3 tor, shall submit to Congress an annual report on
4 national trends in the quality of healthcare provided
5 to the American people.

6 **“SEC. 914. INFORMATION SYSTEMS FOR HEALTHCARE IM-**
7 **PROVEMENT.**

8 “‘In order to foster a range of innovative approaches
9 to the management and communication of health informa-
10 tion, the Agency shall support research to evaluate and
11 initiatives to advance—

12 “(1) the use of information systems for the
13 study of healthcare quality, including the generation
14 of both individual provider and plan-level compara-
15 tive performance measures;

16 “(2) training for healthcare practitioners and
17 researchers in the use of information systems;

18 “(3) the creation of effective linkages between
19 various sources of health information, including the
20 development of information networks;

21 “(4) the delivery and coordination of evidence-
22 based healthcare services, using real-time decision-
23 support programs;

1 “(5) the structure, content, definition, and cod-
 2 ing of health information data and medical vocabu-
 3 laries and shall consult with other Federal entities;

4 “(6) the evaluation and use of computer-based
 5 health records in outpatient and inpatient settings
 6 as a personal health record for individual health as-
 7 sessment and maintenance, and for monitoring pub-
 8 lic health and outcomes of care within populations;
 9 and

10 “(7) the protection of individually identifiable
 11 information in health services research and
 12 healthcare quality improvement.

13 **“SEC. 915. RESEARCH SUPPORTING PRIMARY CARE AND**
 14 **ACCESS IN UNDERSERVED AREAS.**

15 “(a) PREVENTIVE SERVICES TASK FORCE.—

16 “(1) PURPOSE.—The Agency shall provide on-
 17 going administrative, research, and technical support
 18 for the operation of the Preventive Services Task
 19 Force. The Agency shall coordinate and support the
 20 dissemination of the Preventive Services Task Force
 21 recommendations.

22 “(2) OPERATION.—The Preventive Services
 23 Task Force shall review the scientific evidence relat-
 24 ed to the effectiveness, appropriateness, and cost-ef-
 25 fectiveness of clinical preventive services for the pur-

pose of developing recommendations, and updating previous recommendations, regarding their usefulness in daily clinical practice. In carrying out its responsibilities under paragraph (1), the Task Force shall not be subject to the provisions of Appendix 2 of title 5, United States Code.

“(b) PRIMARY CARE RESEARCH.—

“(1) IN GENERAL.—There is established within the Agency a Center for Primary Care Research (referred to in this subsection as the ‘Center’) that shall serve as the principal source of funding for primary care research in the Department of Health and Human Services. For purposes of this paragraph, primary care research focuses on the first contact when illness or health concerns arise, the diagnosis, treatment or referral to specialty care, preventive care, and the relationship between the clinician and the patient in the context of the family and community.

“(2) RESEARCH.—In carrying out this section, the Center shall conduct and support research on—

“(A) the nature and characteristics of primary care practice;

“(B) producing evidence for the management of commonly occurring clinical problems;

1 “(C) the management of undifferentiated
2 clinical problems; and

3 “(D) the continuity and coordination of
4 health services.

5 “(3) DEMONSTRATION.—The Agency shall sup-
6 port demonstrations into the use of new information
7 tools aimed at improving shared decision-making be-
8 tween patients and their care-givers.

9 **“SEC. 916. CLINICAL PRACTICE AND TECHNOLOGY INNOVA-**
10 **TION.**

11 “(a) IN GENERAL.—The Director shall promote inno-
12 vation in evidence-based clinical practice and healthcare
13 technologies by—

14 “(1) conducting and supporting research on the
15 development, diffusion, and use of healthcare tech-
16 nology;

17 “(2) developing, evaluating, and disseminating
18 methodologies for healthcare practice and technology
19 assessment;

20 “(3) conducting intramural and supporting ex-
21 tramural assessments of existing and new healthcare
22 practices and technologies;

23 “(4) promoting education, training, and provid-
24 ing technical assistance in the use of healthcare

1 practice and healthcare technology assessment meth-
 2 odologies and results; and

3 “(5) working with the National Library of Med-
 4 icine and the public and private sector to develop an
 5 electronic clearinghouse of currently available assess-
 6 ments and those in progress.

7 “(b) SPECIFICATION OF PROCESS.—

8 “(1) IN GENERAL.—Not later than June 1,
 9 1999, the Director shall develop and publish a de-
 10 scription of the methods used by the Agency and its
 11 contractors for practice and technology assessment.

12 “(2) CONSULTATIONS.—In carrying out this
 13 subsection, the Director shall cooperate and consult
 14 with the Administrator of the Health Care Financ-
 15 ing Administration, the Director of the National In-
 16 stitutes of Health, the Commissioner of Food and
 17 Drugs, and the heads of any other interested Fed-
 18 eral department or agency, professional societies,
 19 and other private and public entities.

20 “(3) METHODOLOGY.—The methods employed
 21 in practice and technology assessments under para-
 22 graph (1) shall consider—

23 “(A) safety, efficacy, and effectiveness;

24 “(B) legal, social, and ethical implications;

25 “(C) costs, benefits, and cost-effectiveness;

1 “(D) comparisons to alternative tech-
2 nologies and practices; and

3 “(E) requirements of Food and Drug Ad-
4 ministration approval to avoid duplication.

5 “(c) SPECIFIC ASSESSMENTS.—

6 “(1) IN GENERAL.—The Director shall conduct
7 and support specific assessments of healthcare tech-
8 nologies and practices.

9 “(2) GRANTS AND CONTRACTS.—The Director
10 may make grants to, or enter into cooperative agree-
11 ments or contracts with, entities described in para-
12 graph (3) for the establishment of collaborative ar-
13 rangements for the purpose of conducting assess-
14 ments of experimental, emerging, existing, or poten-
15 tially outmoded healthcare technologies, and for re-
16 lated activities.

17 “(3) ELIGIBLE ENTITIES.—An entity described
18 in this paragraph is an entity that is determined to
19 be appropriate by the Director, including academic
20 medical centers, research institutions, professional
21 organizations, third party payers, other govern-
22 mental agencies, and consortia of appropriate re-
23 search entities established for the purpose of con-
24 ducting technology assessments.

1 **“SEC. 917. COORDINATION OF FEDERAL GOVERNMENT**
2 **QUALITY IMPROVEMENT EFFORTS.**

3 “(a) REQUIREMENT.—

4 “(1) IN GENERAL.—The Secretary, acting
5 through the Director, shall coordinate all research,
6 evaluations, and demonstrations related to health
7 services research and quality measurement and im-
8 provement activities undertaken and supported by
9 the Federal Government.

10 “(2) SPECIFIC ACTIVITIES.—The Director, in
11 collaboration with the appropriate Federal officials
12 representing all concerned executive agencies and de-
13 partments, shall develop and manage a process to—

14 “(A) improve interagency coordination, pri-
15 ority setting, and the use and sharing of re-
16 search findings and data pertaining to Federal
17 quality improvement programs and health serv-
18 ices research;

19 “(B) strengthen the research information
20 infrastructure, including databases, pertaining
21 to Federal health services research and
22 healthcare quality improvement initiatives;

23 “(C) set specific goals for participating
24 agencies and departments to further health
25 services research and healthcare quality im-
26 provement; and

1 “(D) strengthen the management of Fed-
2 eral healthcare quality improvement programs.

3 “(b) STUDY BY THE INSTITUTE OF MEDICINE.—

4 “(1) IN GENERAL.—To provide the Department
5 of Health and Human Services with independent, ex-
6 pert advice in redesigning its quality oversight func-
7 tions, and pertinent research programs, the Sec-
8 retary shall enter into a contract with the Institute
9 of Medicine—

10 “(A) to describe and evaluate current qual-
11 ity improvement research and monitoring proc-
12 esses through—

13 “(i) an overview of pertinent health
14 services research activities and quality im-
15 provement efforts with particular attention
16 paid to those performed by the peer review
17 organizations;

18 “(ii) an analysis of the various part-
19 nership activities that the Department of
20 Health and Human Services has pursued
21 with private sector accreditation and other
22 quality measurement organizations;

23 “(iii) the exploration of programmatic
24 areas where partnership activities could be
25 pursued to improve quality oversight of the

1 medicare and medicaid programs under ti-
2 tles XVIII and XIX of the Social Security
3 Act; and

4 “(iv) an identification of opportunities
5 for enhancing health system efficiency
6 through simplification and reduction in re-
7 dundancy of public and private sector qual-
8 ity improvement efforts; and

9 “(B) to identify options and make rec-
10 ommendations to improve the efficiency and ef-
11 fectiveness of such quality improvement pro-
12 grams and to optimize public/private sector ac-
13 creditation bodies through—

14 “(i) the improved coordination of ac-
15 tivities across the medicare and medicaid
16 programs under titles XVIII and XIX of
17 the Social Security Act and various health
18 services research programs;

19 “(ii) greater consistency and stand-
20 ardization of oversight activities across tra-
21 ditional fee-for-service and managed care
22 components of these programs;

23 “(iii) the strengthening of patient
24 choice and participation by incorporating
25 state-of-the-art quality monitoring tools

1 and making information on quality avail-
2 able; and

3 “(iv) the enhancement of the most ef-
4 fective programs, consolidation as appro-
5 priate, and elimination of duplicative ac-
6 tivities within various federal agencies.

7 “(2) REQUIREMENTS.—

8 “(A) IN GENERAL.—The Secretary shall
9 enter into a contract with the Institute of Medi-
10 cine for the preparation—

11 “(i) not later than 12 months after
12 the date of enactment of this title, of a re-
13 port providing an overview of the quality
14 improvement programs of the Department
15 of Health and Human Services for the
16 medicare, medicaid, and CHIP programs
17 under titles XVIII, XIX, and XXI of the
18 Social Security Act; and

19 “(ii) not later than 24 months after
20 the date of enactment of this title, of a
21 final report containing recommendations
22 for a comprehensive system and public-pri-
23 vate partnerships for healthcare quality
24 improvement.

“(B) REPORTS.—The Secretary shall submit the reports described in subparagraph (A) to the Committee on Finance and the Committee on Labor and Human Resources of the Senate and the Committee on Ways and Means and the Committee on Commerce of the House of Representatives.

“PART C—GENERAL PROVISIONS

“SEC. 921. ADVISORY COUNCIL FOR HEALTHCARE QUALITY.

“(a) ESTABLISHMENT.—There is established an advisory council to be known as the Advisory Council for Healthcare Quality.

“(b) DUTIES.—

“(1) IN GENERAL.—The Advisory Council shall advise the Secretary and the Director with respect to activities to carry out the purpose of the Agency under section 901(b).

“(2) CERTAIN RECOMMENDATIONS.—Activities of the Advisory Council under paragraph (1) shall include making recommendations to the Director regarding—

“(A) priorities regarding healthcare research, especially studies related to quality, outcomes, cost and the utilization of, and access to, healthcare services;

1 “(B) the field of healthcare research and
 2 related disciplines, especially issues related to
 3 training needs, and dissemination of informa-
 4 tion on quality; and

5 “(C) the appropriate role of the Agency in
 6 each of these areas in light of private sector ac-
 7 tivity and identification of opportunities for
 8 public-private sector partnerships.

9 “(c) MEMBERSHIP.—

10 “(1) IN GENERAL.—The Advisory Council shall,
 11 in accordance with this subsection, be composed of
 12 appointed members and ex officio members. All
 13 members of the Advisory Council shall be voting
 14 members other than the individuals designated
 15 under paragraph (3)(B) who shall be ex officio mem-
 16 bers of the Advisory Council.

17 “(2) APPOINTED MEMBERS.—The Secretary
 18 shall appoint to the Advisory Council 21 appro-
 19 priately qualified individuals. At least 17 members of
 20 the Advisory Council shall be representatives of the
 21 public who are not officers or employees of the
 22 United States. The Secretary shall ensure that the
 23 appointed members of the Council, as a group, are
 24 representative of professions and entities concerned
 25 with, or affected by, activities under this title and

1 under section 1142 of the Social Security Act. Of
2 such members—

3 “(A) 4 shall be individuals distinguished in
4 the conduct of research, demonstration projects,
5 and evaluations with respect to healthcare;

6 “(B) 4 shall be individuals distinguished in
7 the practice of medicine of which at least 1
8 shall be a primary care practitioner;

9 “(C) 3 shall be individuals distinguished in
10 the health professions;

11 “(D) 4 shall be individuals either rep-
12 resenting the private healthcare sector, includ-
13 ing health plans, providers, and purchasers or
14 individuals distinguished as administrators of
15 healthcare delivery systems;

16 “(E) 4 shall be individuals distinguished in
17 the fields of healthcare quality improvement, ec-
18 onomics, information systems, law, ethics, busi-
19 ness, or public policy; and

20 “(F) 2 shall be individuals representing the
21 interests of patients and consumers of
22 healthcare.

23 “(3) EX OFFICIO MEMBERS.—The Secretary
24 shall designate as ex officio members of the Advisory
25 Council—

1 “(A) the Director of the National Insti-
2 tutes of Health, the Director of the Centers for
3 Disease Control and Prevention, the Adminis-
4 trator of the Health Care Financing Adminis-
5 tration, the Assistant Secretary of Defense
6 (Health Affairs), and the Chief Medical Officer
7 of the Department of Veterans Affairs; and

8 “(B) such other Federal officials as the
9 Secretary may consider appropriate.

10 “(d) TERMS.—Members of the Advisory Council ap-
11 pointed under subsection (c)(2) shall serve for a term of
12 3 years. A member of the Council appointed under such
13 subsection may continue to serve after the expiration of
14 the term of the members until a successor is appointed.

15 “(e) VACANCIES.—If a member of the Advisory
16 Council appointed under subsection (c)(2) does not serve
17 the full term applicable under subsection (d), the individ-
18 ual appointed to fill the resulting vacancy shall be ap-
19 pointed for the remainder of the term of the predecessor
20 of the individual.

21 “(f) CHAIR.—The Director shall, from among the
22 members of the Advisory Council appointed under sub-
23 section (c)(2), designate an individual to serve as the chair
24 of the Advisory Council.

1 “(g) MEETINGS.—The Advisory Council shall meet
2 not less than once during each discrete 4-month period
3 and shall otherwise meet at the call of the Director or the
4 chair.

5 “(h) COMPENSATION AND REIMBURSEMENT OF EX-
6 PENSES.—

7 “(1) APPOINTED MEMBERS.—Members of the
8 Advisory Council appointed under subsection (c)(2)
9 shall receive compensation for each day (including
10 travel time) engaged in carrying out the duties of
11 the Advisory Council unless declined by the member.
12 Such compensation may not be in an amount in ex-
13 cess of the maximum rate of basic pay payable for
14 GS–18 of the General Schedule.

15 “(2) EX OFFICIO MEMBERS.—Officials des-
16 ignated under subsection (c)(3) as ex officio mem-
17 bers of the Advisory Council may not receive com-
18 pensation for service on the Advisory Council in ad-
19 dition to the compensation otherwise received for du-
20 ties carried out as officers of the United States.

21 “(i) STAFF.—The Director shall provide to the Advi-
22 sory Council such staff, information, and other assistance
23 as may be necessary to carry out the duties of the Council.

1 **“SEC. 922. FOUNDATION FOR HEALTHCARE RESEARCH.**

2 “(a) IN GENERAL.—The Secretary shall, acting
3 through the Director of the Agency for Healthcare Qual-
4 ity, establish a nonprofit corporation to be known as the
5 Foundation for Healthcare Research (hereafter in this sec-
6 tion referred to as the ‘Foundation’). The Foundation
7 shall not be an agency or instrumentality of the United
8 States Government.

9 “(b) PURPOSE OF FOUNDATION.—The purpose of
10 the Foundation shall be to—

11 “(1) support the Agency for Healthcare Quality
12 in its mission;

13 “(2) foster public-private partnerships to sup-
14 port the programs and activities of the Agency;

15 “(3) advance collaboration with healthcare re-
16 searchers from universities, industry, and nonprofit
17 organizations; and

18 “(4) develop linkages with users of healthcare
19 and quality research, including patients, consumers,
20 practitioners and other healthcare providers, health
21 plans and insurers, large private or public sector
22 purchasers of healthcare, healthcare policy makers,
23 and healthcare educators.

24 “(c) CERTAIN ACTIVITIES OF FOUNDATION.—In car-
25 rying out subsection (b), the Foundation may solicit and
26 accept gifts, grants, and other donations, establish ac-

1 counts, and invest and expend funds in support of a broad
2 range of research, training, dissemination, and other ac-
3 tivities with respect to the purpose described in such sub-
4 section. In addition, the Foundation is authorized to sup-
5 port the following:

6 “(1) A program to provide and administer en-
7 dowed positions that are associated with the re-
8 search program of the Agency for Healthcare Qual-
9 ity. Such endowments may be expended for the com-
10 pensation of individuals holding the positions, for
11 staff, equipment, quarters, travel, and other expendi-
12 tures that are appropriate in supporting the en-
13 dowed positions.

14 “(2) A program to provide and administer fel-
15 lowships and grants to research personnel in order
16 to work and study in association with the Agency for
17 Healthcare Quality. Such fellowships and grants
18 may include stipends, travel, health insurance bene-
19 fits, and other appropriate expenses. The recipients
20 of fellowships shall be selected by the donors and the
21 Foundation upon the recommendation of the Agency
22 for Healthcare Quality, and shall be subject to the
23 agreement of the Director of the Agency for
24 Healthcare Quality and the Executive Director of
25 the Foundation.

1 “(d) GENERAL STRUCTURE OF FOUNDATION; NON-
2 PROFIT STATUS.—

3 “(1) BOARD OF DIRECTORS.—The Foundation
4 shall have a Board of Directors (in this section re-
5 ferred to as the Board), which shall be established
6 and conducted in accordance with subsection (e).
7 The Board shall establish the general policies of the
8 Foundation for carrying out subsection (b), includ-
9 ing the establishment of the bylaws of the Founda-
10 tion.

11 “(2) EXECUTIVE DIRECTOR.—The Foundation
12 shall have an executive director (in this section re-
13 ferred to as the ‘Director’), who shall be appointed
14 by the Board, who shall serve at the pleasure of the
15 Board, and for whom the Board shall establish the
16 rate of compensation. Subject to compliance with the
17 policies and bylaws established by the Board pursu-
18 ant to paragraph (1), the Director shall be respon-
19 sible for the daily operations of the Foundation in
20 carrying out subsection (b).

21 “(3) NONPROFIT STATUS.—In carrying out
22 subsection (b), the Board shall establish such poli-
23 cies and bylaws under paragraph (1), and the Direc-
24 tor shall carry out such activities under paragraph

1 (2), as may be necessary to ensure that the Founda-
2 tion maintains status as an organization that—

3 “(A) is described in subsection (c)(3) of
4 section 501 of the Internal Revenue Code of
5 1986; and

6 “(B) is, under subsection (a) of such sec-
7 tion, exempt from taxation.

8 “(e) BOARD OF DIRECTORS.—

9 “(1) CERTAIN BYLAWS.—

10 “(A) IN GENERAL.—The Board shall en-
11 sure that bylaws established under subsection
12 (a)(1) include bylaws for the following:

13 “(i) Policies for the selection of the
14 officers, employees, agents, and contractors
15 of the Foundation.

16 “(ii) Policies, including ethical stand-
17 ards, for the acceptance and disposition of
18 donations to the Foundation and for the
19 disposition of the assets of the Foundation.

20 “(iii) Policies for the conduct of the
21 general operations of the Foundation.

22 “(iv) Policies for writing, editing,
23 printing, and publishing of books and other
24 materials, and the acquisition of patents

1 and licenses for devices and procedures de-
2 veloped by the Foundation.

3 “(B) REQUIREMENTS.—The Board shall
4 ensure that the bylaws established under sub-
5 section (d)(1) (and activities carried out under
6 such bylaws) do not—

7 “(i) reflect unfavorably upon the abil-
8 ity of the Foundation, or the Agency for
9 Healthcare Quality, to carry out its re-
10 sponsibilities or official duties in a fair and
11 objective manner; or

12 “(ii) compromise, or appear to com-
13 promise, the integrity of any governmental
14 program or any officer or employee in-
15 volved in such program.

16 “(2) COMPOSITION.—

17 “(A) IN GENERAL.—Subject to subpara-
18 graph (B), the Board shall be composed of 7 in-
19 dividuals, appointed in accordance with para-
20 graph (4), who collectively possess education or
21 experience appropriate for representing the con-
22 stituencies described in subsection (b). Each
23 such individual shall be a voting member of the
24 Board.

1 “(B) ADDITIONAL MEMBERS.—The Board
 2 may, through amendments to the bylaws of the
 3 Foundation, provide that the number of mem-
 4 bers of the Board shall be a greater number
 5 than the number specified in subparagraph (A).

6 “(3) CHAIR.—The Board shall, from among the
 7 members of the Board, designate an individual to
 8 serve as the chair of the Board (in this subsection
 9 referred to as the ‘Chair’).

10 “(4) APPOINTMENTS, VACANCIES, AND
 11 TERMS.—The following shall apply to the Board:

12 “(A) Any vacancy in the membership of
 13 the Board shall be filled by appointment by the
 14 Board, after consideration of suggestions made
 15 by the Chair and the Director regarding the ap-
 16 pointments. Any such vacancy shall be filled not
 17 later than the expiration of the 180-day period
 18 beginning on the date on which the vacancy oc-
 19 curs.

20 “(B) The term of office of each member of
 21 the Board appointed under subparagraph (A)
 22 shall be 5 years. A member of the Board may
 23 continue to serve after the expiration of the
 24 term of the member until the expiration of the

1 180-day period beginning on the date on which
2 the term of the member expires.

3 “(C) A vacancy in the membership of the
4 Board shall not affect the power of the Board
5 to carry out the duties of the Board. If a mem-
6 ber of the Board does not serve the full term
7 applicable under subparagraph (B), the individ-
8 ual appointed to fill the resulting vacancy shall
9 be appointed for the remainder of the term of
10 the predecessor of the individual.

11 “(5) COMPENSATION.—Members of the Board
12 may not receive compensation for service on the
13 Board. The members may be reimbursed for travel,
14 subsistence, and other necessary expenses incurred
15 in carrying out the duties of the Board.

16 “(f) CERTAIN RESPONSIBILITIES OF EXECUTIVE DI-
17 RECTOR.—In carrying out subsection (d)(2), the Director
18 shall carry out the following functions:

19 “(1) Hire, promote, compensate, and discharge
20 officers and employees of the Foundation, and define
21 the duties of the officers and employees.

22 “(2) Accept and administer donations to the
23 Foundation, and administer the assets of the Foun-
24 dation.

1 “(3) Establish a process for the selection of
2 candidates for holding endowed positions under sub-
3 section (c).

4 “(4) Enter into such financial agreements as
5 are appropriate in carrying out the activities of the
6 Foundation.

7 “(5) Take such action as may be necessary to
8 acquire patents and licenses for devices and proce-
9 dures developed by the Foundation and the employ-
10 ees of the Foundation.

11 “(6) Adopt, alter, and use a corporate seal,
12 which shall be judicially noticed.

13 “(7) Commence and respond to judicial pro-
14 ceedings in the name of the Foundation.

15 “(8) Other functions that are appropriate in the
16 determination of the Director.

17 “(g) GENERAL PROVISIONS.—

18 “(1) AUTHORITY FOR ACCEPTING FUNDS.—The
19 Director of the Agency for Healthcare Quality may
20 accept and utilize, on behalf of the Federal Govern-
21 ment, any gift, donation, bequest, or devise of real
22 or personal property from the Foundation for the
23 purpose of aiding or facilitating the work of such
24 Agency. Funds may be accepted and utilized by such
25 Director under the preceding sentence without re-

1 gard to whether the funds are designated as general-
2 purpose funds or special-purpose funds. Any funds
3 transferred under this paragraph shall be subject to
4 all Federal limitations relating to federally funded
5 research.

6 “(2) AUTHORITY FOR ACCEPTANCE OF VOL-
7 UNTARY SERVICES.—

8 “(A) IN GENERAL.—The Director of the
9 Agency for Healthcare Quality may accept, on
10 behalf of the Federal Government, any vol-
11 untary services provided to such Agency by the
12 Foundation for the purpose of aiding or facili-
13 tating the work of such Agency. In the case of
14 an individual, such Director may accept the
15 services provided under the preceding sentence
16 by the individual for not more than 2 years.

17 “(B) LIMITATION.—The limitation estab-
18 lished in subparagraph (A) regarding the period
19 of time in which services may be accepted ap-
20 plies to each individual who is not an employee
21 of the Federal Government and who serves in
22 association with the Agency for Healthcare
23 Quality pursuant to financial support from the
24 Foundation.

1 “(3) ADMINISTRATIVE CONTROL.—No officer,
2 employee, or member of the Board of the Founda-
3 tion may exercise any administrative or managerial
4 control over any Federal employee.

5 “(4) APPLICABILITY OF CERTAIN STANDARDS
6 TO NON-FEDERAL EMPLOYEES.—In the case of any
7 individual who is not an employee of the Federal
8 Government and who serves in association with the
9 Agency for Healthcare Quality pursuant to financial
10 support from the Foundation, the Foundation shall
11 negotiate a memorandum of understanding with the
12 individual and the Director of the Agency for
13 Healthcare Quality specifying that the individual—

14 “(A) shall be subject to the ethical and
15 procedural standards regulating Federal em-
16 ployment, scientific investigation, and research
17 findings (including publications and patents)
18 that are required of individuals employed by the
19 Agency for Healthcare Quality, including stand-
20 ards under this Act, the Ethics in Government
21 Act, and the Technology Transfer Act; and

22 “(B) shall be subject to such ethical and
23 procedural standards under chapter 11 of title
24 18, United States Code (relating to conflicts of
25 interest), as the Director of such Agency deter-

1 mines is appropriate, except such memorandum
 2 may not provide that the individual shall be
 3 subject to the standards of section 209 of such
 4 chapter.

5 “(5) FINANCIAL CONFLICTS OF INTEREST.—
 6 Any individual who is an officer, employee, or mem-
 7 ber of the Board of the Foundation may not directly
 8 or indirectly participate in the consideration or de-
 9 termination by the Foundation of any question af-
 10 fecting—

11 “(A) any direct or indirect financial inter-
 12 est of the individual; or

13 “(B) any direct or indirect financial inter-
 14 est of any business organization or other entity
 15 of which the individual is an officer or employee
 16 or in which the individual has a direct or indi-
 17 rect financial interest.

18 “(6) AUDITS; AVAILABILITY OF RECORDS.—The
 19 Foundation shall—

20 “(A) provide for biennial audits of the fi-
 21 nancial condition of the Foundation; and

22 “(B) make such audits, and all other
 23 records, documents, and other papers of the
 24 Foundation, available to the Secretary and the

1 Comptroller General of the United States for
2 examination or audit.

3 “(7) REPORTS.—

4 “(A) IN GENERAL.—Not later than Feb-
5 ruary 1 of each fiscal year, the Foundation
6 shall publish a report describing the activities of
7 the Foundation during the preceding fiscal
8 year. Each such report shall include for the fis-
9 cal year involved a comprehensive statement of
10 the operations, activities, financial condition,
11 and accomplishments of the Foundation.

12 “(B) FINANCIAL REQUIREMENT.—With re-
13 spect to the financial condition of the Founda-
14 tion, each report under subparagraph (A) shall
15 include the source, and a description of, all gifts
16 to the Foundation of real or personal property,
17 and the source and amount of all gifts to the
18 Foundation of money. Each such report shall
19 include a specification of any restrictions on the
20 purposes for which gifts to the Foundation may
21 be used.

22 “(C) PUBLIC INSPECTION.—The Founda-
23 tion shall make copies of each report submitted
24 under subparagraph (A) available for public in-
25 spection, and shall upon request provide a copy

1 of the report to any individual for a charge not
 2 exceeding the cost of providing the copy.

3 “(8) LIAISON FROM THE AGENCY FOR
 4 HEALTHCARE QUALITY.—The Director of the Agen-
 5 cy for Healthcare Quality shall serve as the liaison
 6 representative of such Agency and the Foundation.

7 “(h) FEDERAL FUNDING.—

8 “(1) AUTHORITY FOR FINANCIAL SUPPORT.—

9 “(A) IN GENERAL.—The Secretary, acting
 10 through the Director of the Agency for
 11 Healthcare Quality, shall—

12 “(i) for fiscal year 1999, support the
 13 work of the Committee, established pursu-
 14 ant to subsection (i); and

15 “(ii) for fiscal year 2000 and each
 16 subsequent fiscal year, make a grant to the
 17 Foundation.

18 “(B) LIMITATIONS.—Financial support
 19 under subparagraph (A) may be expended—

20 “(i) in the case of the Committee,
 21 only for the purpose of carrying out the
 22 duties established in subsection (i); and

23 “(ii) in the case of the Foundation,
 24 only for the purpose of the administrative
 25 expenses of the Foundation.

“(C) REMAINING FUNDS.—For the purposes described in subparagraph (B), any portion of the financial support provided to the Committee under subparagraph (A)(i) for fiscal year 1999 that remains unobligated after the Committee completes the duties established in subsection (i) shall be available to the Foundation.

“(2) FUNDS.—

“(A) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of providing financial support under paragraph (1), there is authorized to be appropriated for the Foundation \$500,000 for each fiscal year.

“(B) GRANTS.—For the purpose of grants under paragraph (1), the Secretary may for each fiscal year make available not more than \$500,000 from the amounts appropriated for the fiscal year for the programs of the Department of Health and Human Services. Such amounts may be made available without regard to whether amounts have been appropriated under subparagraph (A).

“(3) CERTAIN RESTRICTION.—If the Foundation receives Federal funds for the purpose of serv-

1 ing as a fiscal intermediary between Federal agen-
 2 cies, the Foundation may not receive such funds for
 3 the indirect costs of carrying out such purpose in an
 4 amount exceeding 10 percent of the direct costs of
 5 carrying out such purpose. The preceding sentence
 6 may not be construed as authorizing the expenditure
 7 of any grant under paragraph (1) for such purpose.

8 “(i) ESTABLISHMENT OF COMMITTEE.—

9 “(1) IN GENERAL.—The Secretary shall estab-
 10 lish in accordance with this subsection a committee
 11 (referred to in this subsection as the ‘Committee’) to
 12 carry out the functions described in paragraph (2).

13 “(2) FUNCTIONS.—The functions referred to in
 14 paragraph (1) for the Committee are as follows:

15 “(A) To carry out such activities as may
 16 be necessary to incorporate the Foundation
 17 under the laws of the State involved, including
 18 serving as incorporators for the Foundation.
 19 Such activities shall include ensuring that the
 20 articles of incorporation for the Foundation re-
 21 quire that the Foundation be established and
 22 operated in accordance with the applicable pro-
 23 visions of this part (or any successor to this
 24 part), including such provisions as may be in
 25 effect pursuant to amendments enacted after

1 the date of the enactment of the Healthcare
2 Quality Enhancement Act of 1998.

3 “(B) To ensure that the Foundation quali-
4 fies for and maintains the status described in
5 subsection (d)(3) (regarding taxation).

6 “(C) To establish the general policies and
7 initial bylaws of the Foundation, which bylaws
8 shall include the bylaws described in subsections
9 (d)(3) and (e)(1).

10 “(D) To provide for the initial operation of
11 the Foundation, including providing for quar-
12 ters, equipment, and staff.

13 “(E) To appoint the initial members of the
14 Board in accordance with the requirements es-
15 tablished in subsection (e)(2)(A) for the com-
16 position of the Board and establish their respec-
17 tive terms, and other such qualifications as the
18 Committee may determine to be appropriate.

19 “(3) COMPLETION OF FUNCTIONS OF COMMIT-
20 TEE; INITIAL MEETING OF BOARD.—

21 “(A) IN GENERAL.—The Committee shall
22 complete the functions required in paragraph
23 (1) not later than 1 year following the appoint-
24 ment of the last member of the Committee. The
25 Committee shall terminate upon the expiration

1 of the 30-day period beginning on the date on
2 which the Secretary determines that the func-
3 tions have been completed.

4 “(B) INITIAL MEETING.—The initial meet-
5 ing of the Board shall be held not later than 90
6 days after the Committee has completed its
7 functions.

8 “(4) COMPOSITION.—The Committee shall be
9 composed of 7 members, each of whom shall be a
10 voting member. Of the members of the Committee—

11 “(A) not fewer than 2 members shall have
12 broad, general experience in healthcare; and

13 “(B) not fewer than 2 members shall have
14 broad, general experience in the creation of a
15 nonprofit private organization, one of whom
16 shall have expertise in the legal structuring of
17 nonprofit organizations (without regard to
18 whether the individuals have experience in
19 healthcare).

20 “(5) CHAIR.—The Committee shall, from
21 among the members of the Committee, designate an
22 individual to serve as the chair of the Committee.

23 “(6) TERMS; VACANCIES.—The term of mem-
24 bers of the Committee shall be for the duration of
25 the Committee. A vacancy in the membership of the

1 Committee shall not affect the power of the Commit-
 2 tee to carry out the duties of the Committee. If a
 3 member of the Committee does not serve the full
 4 term, the individual appointed to fill the resulting
 5 vacancy shall be appointed for the remainder of the
 6 term of the predecessor of the individual.

7 “(7) COMPENSATION.—Members of the Com-
 8 mittee may not receive compensation for service on
 9 the Committee. Members of the Committee may be
 10 reimbursed for travel, subsistence, and other nec-
 11 essary expenses incurred in carrying out the duties
 12 of the Committee.

13 “(8) COMMITTEE SUPPORT.—The Director of
 14 the Agency for Healthcare Quality may, from
 15 amounts available to the Director for the general ad-
 16 ministration of such Agency, provide staff and finan-
 17 cial support to assist the Committee with carrying
 18 out the functions described in paragraph (2). In pro-
 19 viding such staff and support, the Director may both
 20 detail employees and contract for assistance.

21 **“SEC. 923. PEER REVIEW WITH RESPECT TO GRANTS AND**
 22 **CONTRACTS.**

23 “(a) REQUIREMENT OF REVIEW.—

24 “(1) IN GENERAL.—Appropriate technical and
 25 scientific peer review shall be conducted with respect

1 to each application for a grant, cooperative agree-
2 ment, or contract under this title.

3 “(2) REPORTS TO DIRECTOR.—Each peer re-
4 view group to which an application is submitted pur-
5 suant to paragraph (1) shall report its finding and
6 recommendations respecting the application to the
7 Director in such form and in such manner as the
8 Director shall require.

9 “(b) APPROVAL AS PRECONDITION OF AWARDS.—
10 The Director may not approve an application described in
11 subsection (a)(1) unless the application is recommended
12 for approval by a peer review group established under sub-
13 section (c).

14 “(c) ESTABLISHMENT OF PEER REVIEW GROUPS.—

15 “(1) IN GENERAL.—The Director shall establish
16 such technical and scientific peer review groups as
17 may be necessary to carry out this section. Such
18 groups shall be established without regard to the
19 provisions of title 5, United States Code, that govern
20 appointments in the competitive service, and without
21 regard to the provisions of chapter 51, and sub-
22 chapter III of chapter 53, of such title that relate
23 to classification and pay rates under the General
24 Schedule.

1 “(2) MEMBERSHIP.—The members of any peer
2 review group established under this section shall be
3 appointed from among individuals who by virtue of
4 their training or experience are eminently qualified
5 to carry out the duties of such peer review group.
6 Officers and employees of the United States may not
7 constitute more than 25 percent of the membership
8 of any such group. Such officers and employees may
9 not receive compensation for service on such groups
10 in addition to the compensation otherwise received
11 for duties carried out as such officers and employ-
12 ees.

13 “(3) DURATION.—Notwithstanding section
14 14(a) of the Federal Advisory Committee Act, peer
15 review groups established under this section shall
16 continue in existence until otherwise provided by
17 law.

18 “(4) QUALIFICATIONS.—Members of any peer-
19 review group shall, at a minimum, meet the follow-
20 ing requirements:

21 “(A) Such members shall agree in writing
22 to treat information received, records, reports,
23 and recommendations as confidential informa-
24 tion.

1 “(B) Such members shall agree in writing
2 to recuse themselves from participation in the
3 peer-review of specific applications which
4 present a potential personal conflict of interest
5 or appearance of such conflict, including em-
6 ployment in the applicant organization, stock
7 ownership, or any financial or other arrange-
8 ment that might introduce bias in the process
9 of peer-review.

10 “(d) AUTHORITY FOR PROCEDURAL ADJUSTMENTS
11 IN CERTAIN CASES.—In the case of applications described
12 in subsection (a)(1) for financial assistance whose direct
13 costs will not exceed \$100,000, the Director may make
14 appropriate adjustments in the procedures otherwise es-
15 tablished by the Director for the conduct of peer review
16 under this section. Such adjustments may be made for the
17 purpose of encouraging the entry of individuals into the
18 field of research, for the purpose of encouraging clinical
19 practice-oriented research, and for such other purposes as
20 the Director may determine to be appropriate.

21 “(e) REGULATIONS.—The Secretary shall issue regu-
22 lations for the conduct of peer review under this section.

1 **“SEC. 924. CERTAIN PROVISIONS WITH RESPECT TO DEVEL-**
2 **OPMENT, COLLECTION, AND DISSEMINATION**
3 **OF DATA.**

4 “(a) STANDARDS WITH RESPECT TO UTILITY OF
5 DATA.—

6 “(1) IN GENERAL.—With respect to data devel-
7 oped or collected by any entity for the purpose de-
8 scribed in section 901(b), the Director shall, in order
9 to assure that utility, accuracy, and sufficiency of
10 such data for all interested entities, establish rec-
11 ommendations for methods of developing and collect-
12 ing such data. Such recommendations shall include
13 recommendations for the development and collection
14 of data on the outcomes of healthcare services and
15 procedures. Such recommendations shall recognize
16 the differences between types of healthcare plans,
17 delivery systems, healthcare providers, and provider
18 arrangements.

19 “(2) RELATIONSHIP WITH MEDICARE PRO-
20 GRAM.—In any case where recommendations under
21 paragraph (1) may affect the administration of the
22 program under title XVIII of the Social Security
23 Act, they shall be in the form of recommendations
24 to the Secretary for such program.

25 “(b) STATISTICS.—The Director shall—

1 “(1) take such action as may be necessary to
 2 assure that statistics developed under this title are
 3 of high quality, timely, and comprehensive, as well
 4 as specific, standardized, and adequately analyzed
 5 and indexed; and

6 “(2) publish, make available, and disseminate
 7 such statistics on as wide a basis as is practicable.

8 “(c) **AUTHORITY REGARDING CERTAIN REQUESTS.—**
 9 Upon request of a public or private entity, the Director
 10 may undertake research or analyses otherwise authorized
 11 by this title pursuant to arrangements under which such
 12 entity will pay the cost of the services provided. Amounts
 13 received by the Director under such arrangements shall
 14 be available to the Director for obligation until expended.

15 **“SEC. 925. DISSEMINATION OF INFORMATION.**

16 “(a) **IN GENERAL.—**The Administrator shall—

17 “(1) without regard to section 501 of title 44,
 18 United States Code, promptly publish, make avail-
 19 able, and otherwise disseminate, in a form under-
 20 standable and on as broad a basis as practicable so
 21 as to maximize its use, the results of research, dem-
 22 onstration projects, and evaluations conducted or
 23 supported under this title;

1 “(2) promptly make available to the public data
2 developed in such research, demonstration projects,
3 and evaluations;

4 “(3) building upon information services pro-
5 vided by the National Library of Medicine and con-
6 sidering applicable interagency agreements, provide
7 indexing, abstracting, translating, publishing, and
8 other services leading to a more effective and timely
9 dissemination of information on research, dem-
10 onstration projects, and evaluations with respect to
11 healthcare to public and private entities and individ-
12 uals engaged in the improvement of healthcare deliv-
13 ery and the general public, and undertake programs
14 to develop new or improved methods for making
15 such information available; and

16 “(4) as appropriate, provide technical assistance
17 to State and local government and health agencies
18 and conduct liaison activities to such agencies to fos-
19 ter dissemination.

20 “(b) PROHIBITION AGAINST RESTRICTIONS.—Except
21 as provided in subsection (c), the Director may not restrict
22 the publication or dissemination of data from, or the re-
23 sults of, projects conducted or supported under this title.

24 “(c) LIMITATION ON USE OF CERTAIN INFORMA-
25 TION.—No information, if an establishment or person sup-

1 plying the information or described in it is identifiable,
 2 obtained in the course of activities undertaken or sup-
 3 ported under this title may be used for any purpose other
 4 than the purpose for which it was supplied unless such
 5 establishment or person has consented (as determined
 6 under regulations of the Director) to its use for such other
 7 purpose. Such information may not be published or re-
 8 leased in other form if the person who supplied the infor-
 9 mation or who is described in it is identifiable unless such
 10 person has consented (as determined regulations of the
 11 Director) to its publication or release in other form.

12 “(d) PENALTY.—Any person who violates subsection
 13 (c) shall be subject to a civil monetary penalty of not more
 14 than \$10,000 for each such violation involved. Such pen-
 15 alty shall be imposed and collected in the same manner
 16 as civil money penalties under subsection (a) of section
 17 1128A of the Social Security Act are imposed and col-
 18 lected under that section.

19 **“SEC. 926. ADDITIONAL PROVISIONS WITH RESPECT TO**
 20 **GRANTS AND CONTRACTS.**

21 “(a) PRIORITIES.—In establishing priorities to carry
 22 out this title, subject to the availability of funds, the Di-
 23 rector shall consider—

1 “(1) the needs and priorities of healthcare pro-
2 grams that are operated by or supported, in whole
3 or in part, by Federal agencies;

4 “(2) the healthcare needs of low-income groups,
5 minority groups, children, the elderly, and persons
6 with special healthcare needs and issues related to
7 the delivery of healthcare services in rural areas (in-
8 cluding frontier areas).

9 “(b) FINANCIAL CONFLICTS OF INTEREST.—With
10 respect to projects for which awards of grants, cooperative
11 agreements, or contracts are authorized to be made under
12 this title, the Director shall by regulation define—

13 “(1) the specific circumstances that constitute
14 financial interests in such projects that will, or may
15 be reasonably expected to, create a bias in favor of
16 obtaining results in the projects that are consistent
17 with such interests; and

18 “(2) the actions that will be taken by the Direc-
19 tor in response to any such interests identified by
20 the Director.

21 “(c) REQUIREMENT OF APPLICATION.—The Director
22 may not, with respect to any program under this title au-
23 thorizing the provision of grants, cooperative agreements,
24 or contracts, provide any such financial assistance unless
25 an application for the assistance is submitted to the Sec-

1 retary and the application is in such form, is made in such
 2 manner, and contains such agreements, assurances, and
 3 information as the Director determines to be necessary to
 4 carry out the program in involved.

5 “(d) PROVISION OF SUPPLIES AND SERVICES IN
 6 LIEU OF FUNDS.—

7 “(1) IN GENERAL.—Upon the request of an en-
 8 tity receiving a grant, cooperative agreement, or con-
 9 tract under this title, the Secretary may, subject to
 10 paragraph (2), provide supplies, equipment, and
 11 services for the purpose of aiding the entity in carry-
 12 ing out the project involved and, for such purpose,
 13 may detail to the entity any officer or employee of
 14 the Department of Health and Human Services.

15 “(2) CORRESPONDING REDUCTION IN FUNDS.—
 16 With respect to a request described in paragraph
 17 (1), the Secretary shall reduce the amount of the fi-
 18 nancial assistance involved by an amount equal to
 19 the costs of detailing personnel and the fair market
 20 value of any supplies, equipment, or services pro-
 21 vided by the Director. The Secretary shall, for the
 22 payment of expenses incurred in complying with
 23 such request, expend the amounts withheld.

24 “(e) APPLICABILITY OF CERTAIN PROVISIONS WITH
 25 RESPECT TO CONTRACTS.—Contracts may be entered into

1 under this part without regard to sections 3648 and 3709
2 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

3 **“SEC. 927. CERTAIN ADMINISTRATIVE AUTHORITIES.**

4 “(a) DEPUTY DIRECTOR AND OTHER OFFICERS AND
5 EMPLOYEES.—

6 “(1) DEPUTY DIRECTOR.—The Director may
7 appoint a deputy director for the Agency.

8 “(2) OTHER OFFICERS AND EMPLOYEES.—The
9 Director may appoint and fix the compensation of
10 such officers and employees as may be necessary to
11 carry out this title. Except as otherwise provided by
12 law, such officers and employees shall be appointed
13 in accordance with the civil service laws and their
14 compensation fixed in accordance with title 5,
15 United States Code.

16 “(b) FACILITIES.—The Secretary, in carrying out
17 this title—

18 “(1) may acquire, without regard to the Act of
19 March 3, 1877 (40 U.S.C. 34), by lease or otherwise
20 through the Director of General Services, buildings
21 or portions of buildings in the District of Columbia
22 or communities located adjacent to the District of
23 Columbia for use for a period not to exceed 10
24 years; and

1 “(2) may acquire, construct, improve, repair,
2 operate, and maintain laboratory, research, and
3 other necessary facilities and equipment, and such
4 other real or personal property (including patents)
5 as the Secretary deems necessary.

6 “(c) PROVISION OF FINANCIAL ASSISTANCE.—The
7 Director, in carrying out this title, may make grants to
8 public and nonprofit entities and individuals, and may
9 enter into cooperative agreements or contracts with public
10 and private entities and individuals.

11 “(d) UTILIZATION OF CERTAIN PERSONNEL AND RE-
12 SOURCES.—

13 “(1) DEPARTMENT OF HEALTH AND HUMAN
14 SERVICES.—The Director, in carrying out this title,
15 may utilize personnel and equipment, facilities, and
16 other physical resources of the Department of
17 Health and Human Services, permit appropriate (as
18 determined by the Secretary) entities and individuals
19 to utilize the physical resources of such Department,
20 and provide technical assistance and advice.

21 “(2) OTHER AGENCIES.—The Director, in car-
22 rying out this title, may use, with their consent, the
23 services, equipment, personnel, information, and fa-
24 cilities of other Federal, State, or local public agen-

1 cies, or of any foreign government, with or without
2 reimbursement of such agencies.

3 “(e) CONSULTANTS.—The Secretary, in carrying out
4 this title, may secure, from time to time and for such peri-
5 ods as the Director deems advisable but in accordance
6 with section 3109 of title 5, United States Code, the as-
7 sistance and advice of consultants from the United States
8 or abroad.

9 “(f) EXPERTS.—

10 “(1) IN GENERAL.—The Secretary may, in car-
11 rying out this title, obtain the services of not more
12 than 50 experts or consultants who have appropriate
13 scientific or professional qualifications. Such experts
14 or consultants shall be obtained in accordance with
15 section 3109 of title 5, United States Code, except
16 that the limitation in such section on the duration
17 of service shall not apply.

18 “(2) TRAVEL EXPENSES.—

19 “(A) IN GENERAL.—Experts and consult-
20 ants whose services are obtained under para-
21 graph (1) shall be paid or reimbursed for their
22 expenses associated with traveling to and from
23 their assignment location in accordance with
24 sections 5724, 5724a(a), 5724a(c), and
25 5726(C) of title 5, United States Code.

1 “(B) LIMITATION.—Expenses specified in
2 subparagraph (A) may not be allowed in con-
3 nection with the assignment of an expert or
4 consultant whose services are obtained under
5 paragraph (1) unless and until the expert
6 agrees in writing to complete the entire period
7 of assignment, or 1 year, whichever is shorter,
8 unless separated or reassigned for reasons that
9 are beyond the control of the expert or consult-
10 ant and that are acceptable to the Secretary. If
11 the expert or consultant violates the agreement,
12 the money spent by the United States for the
13 expenses specified in subparagraph (A) is recov-
14 erable from the expert or consultant as a debt
15 of the United States. The Secretary may waive
16 in whole or in part a right of recovery under
17 this subparagraph.

18 “(g) VOLUNTARY AND UNCOMPENSATED SERV-
19 ICES.—The Director, in carrying out this title, may accept
20 voluntary and uncompensated services.

21 **“SEC. 928. FUNDING.**

22 “(a) INTENT.—To ensure that the United States’s in-
23 vestment in biomedical research is rapidly translated into
24 improvements in the quality of patient care, there must
25 be a corresponding investment in research on the most ef-

1 fective clinical and organizational strategies for use of
2 these findings in daily practice. The authorization levels
3 in subsections (b) and (c) provide for a proportionate in-
4 crease in healthcare research as the United State’s invest-
5 ment in biomedical research increases.

6 “(b) AUTHORIZATION OF APPROPRIATIONS.—For the
7 purpose of carrying out this title, there are authorized to
8 be appropriated \$180,000,000 for fiscal year 1999, and
9 such sums as may be necessary for each of the fiscal years
10 2000 through 2003.

11 “(c) EVALUATIONS.—In addition to amounts avail-
12 able pursuant to subsection (b) for carrying out this title,
13 there shall be made available for such purpose, from the
14 amounts made available pursuant to section 241 (relating
15 to evaluations), an amount equal to 40 percent of the max-
16 imum amount authorized in such section 241 to be made
17 available for a fiscal year.

18 “(d) CENTERS FOR EDUCATION AND RESEARCH ON
19 THERAPEUTICS.—For the purpose of carrying out the
20 demonstration program regarding centers for education
21 and research on therapeutics under section 912(b), there
22 are authorized to be appropriated \$2,000,000 for fiscal
23 year 1998, and \$3,000,000 for fiscal year 1999, and such
24 sums as may be necessary for each of the fiscal years 2000
25 through 2003.

1 **“SEC. 929. DEFINITIONS.**

2 “In this title:

3 “(1) ADVISORY COUNCIL.—The term ‘Advisory
4 Council’ means the Advisory Council on Healthcare
5 Quality established under section 921.

6 “(2) AGENCY.—The term ‘Agency’ means the
7 Agency for Healthcare Quality.

8 “(3) DIRECTOR.—The term ‘Director’ means
9 the Director for the Agency for Healthcare Qual-
10 ity.”.

11 **SEC. 4. REFERENCES.**

12 Effective upon the date of enactment of this Act, any
13 reference in law to the “Agency for Health Care Policy
14 and Research” shall be deemed to be a reference to the
15 “Agency for Healthcare Quality”.

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